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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/692,468	10/22/2003	Qi-Bin Bao	79587	7253
22342 7590 03/04/2009 FITCH EVEN TABIN AND FLANNERY 120 SOUTH LASALLE STREET SUITE 1600 CHICAGO, IL 60603-3406				
EXAMINER				
LEVINE, JOSHUA H				
ART UNIT		PAPER NUMBER		
3774				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/692,468

Applicant(s)

BAO ET AL.

Examiner

JOSHUA LEVINE

Art Unit

3774

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 January 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 3, 4 and 11-51 is/are pending in the application.
- 4a) Of the above claim(s) 4, 11-20, 29, 30 and 49-51 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3, 21-28 and 31-48 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01/07/2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
- Paper No(s)/Mail Date 12/16/2008
- 4) ☐ Interview Summary (PTO-413)
- Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Response to Restriction election

1. This office action is in response to the election of Group I and species pertaining to figures 1 and 3 without traverse. Claims 1, 3, 21-28 and 31-48 read on the selected embodiment and will be examined. Claims 2 and 5-10 are cancelled; claims 4, 11-20, 29-30, and 49-51 are withdrawn, and claims 1-4 and 11-51 are pending in this application.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1, 3, 21-28 are rejected under 35 U.S.C. 102(e) as being anticipated Marnay et al. (6036071).

4. Regarding claim 1, Marnay disclosed a spinal implant comprising a rigid upper shell 2 (figure 1) having a smooth outer surface 5 (figure 1) for facing and non-invasively contacting the natural end plate of the upper vertebra (column 3 lines 56-60) for sliding engagement therewith and sized to fit within the natural annulus of the spinal disc (see claim 1), a rigid lower shell 3 (figure 1) having a smooth lower surface 13 (figure 3) for facing and non-invasively contacting the natural end plate (column 4 lines

9-15) of the lower vertebra for sliding engagement therewith and sized to fit within the natural annulus of the spinal disc (see claim 1), inner surfaces of the upper and lower shells that generally face each other as shown in figure 7, a bearing interface 12 (spherical indentation, figure 7) at at least one of the inner surfaces of one of the shells (see figure 1), and opposite narrow ends of each of the shells (short sides, column 3 lines 64-67, column 4 line 1) and elongated sides of each of the shells extending between the narrow ends thereof so that the sides are longer than the narrow end to allow the shells to be arranged with narrow ends of the shells leading the shells as the shells are inserted through an incision smaller than the elongated sides of the shells so that the natural annulus retains the shells in the intervertebral space. The examiner considers the shell's structure to be rotateable and the leading edge alterable by any surgeon before implantation. The claimed implant's structure is not differentiated from the disclosure of Marnay despite the different disclosed implantation method.

5. Regarding claim 3, Marnay disclosed that the shells are separate members configured to be sequentially inserted through the incision in the annulus, and be assembled within the annulus (column 3 lines 20-24).

6. Regarding claim 21-22, Marnay disclosed at least one of the shells includes a gripping projection 17 (figure 7) configured to allow for tool insertion of the shells via bore 21 (figure 7) through the annulus incision into the intervertebral space and shifting of the shells therein. The gripping projection further comprises gripping posts (pin like extensions, column 4 lines 57-60).

7. Regarding claim 23, Marnay disclosed that the gripping projection includes an arcuate engagement surface, via pin like extensions, and a flat abutment surface via the rectangular face surrounding bore 21 as shown in figure 3.
8. Regarding claim 24, Marnay disclosed that bearing interface comprises engaging concave surface 12 (figure 7) and convex bearing surface 25 (figure 7) portion of the inner surfaces of the upper and lower shells that bear against each other for substantially the entire arcuate extent thereof without discontinuities in the bearing surface portions (column 5 lines 22-25).
9. Regarding claim 25, Marnay disclosed that the inner surfaces further includes flat surface portions 11/16 (figure 1) adjacent the concave and convex surface portions. Surface 11 is disclosed to be substantially parallel to flat face 5 (column 4 lines 5-7)
10. Regarding claim 26, Marnay disclosed a gripping post projecting from at least one of the flat surface portions of the one of the shells (column 4 lines 57-60). The gripping portion extends from the bore 20 (figure 1) in flat portion 16.
11. Regarding claim 27, Marnay disclosed an inner surface of one of the shells including a flat surface portion 11 and a concave surface 12 portion recessed from the flat surface portion, and the inner surface of the other shell includes a flat surface portion 16 and a dome surface 25 (figure 7) projecting beyond the flat surface portion of the other shell.
12. Regarding claim 28, Marnay disclosed that the smooth, outer surfaces of the shells are flat surfaces (column 3 line 56, column 4 lines 10-11).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. Claims 31-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Marnay et al. (6036071) in further view of Erickson (6368350).

14. Regarding claims 31-32, Marnay disclosed a rigid upper shell 2 and a rigid lower shell 3 and a bearing interface 12/25 at portions of the inner surfaces of both shells, and the bearing interface allows relative shifting therebetween (column 5 lines 24-27).

Regarding claim 33, Marnay disclosed multiple articulating load bearing members 12/25 (figure 7), the articulating members having opposing surfaces which are configured to engage and move against each other (column 5 lines 22-27).

Regarding claim 34-35, Marnay disclosed that engaging surfaces are configured to allow for relative turning and sliding movement therebetween (column 5 lines 22-27).

Regarding claim 36, Marnay disclosed that one of the members has a concave bearing surface 12 (figure 7) and another one of the members has a convex bearing surface 25 (figure 7) in engagement with the concave surface.

Regarding claim 37, Marnay disclosed that the members include outer bearing surfaces 5 (figure 7) configured to engage and move relative to bone material engaged therewith.

Regarding claim 38, Marnay disclosed that the concave surface and convex surface are configured to permit polyaxial movement of the members relative to each other as they

are configured to rotate as a ball joint (column 5 lines 22-27).

Regarding claim 39-41, Marnay disclosed members cooperate to form a nucleus device for replacing a nucleus of a spinal disc and are sized to fit within and be retained by a natural annulus of the disc (column 6 lines 32-36).

Erikson teaches the use of PEEK for vertebral implants for load bearing and articular surfaces (column 5 lines 50-64). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention, to include PEEK shells and bearing components, as suggested and taught by Erikson, for the purpose of supplying a non compressible substance that minimizes the amount of seizing in articular components (column 5 lines 49-50, 62-65) .

15. Regarding claim 42, Marnay disclosed an upper load bearing member 2 (figure 7) for being implanted in an intervertebral space within the intact, natural annulus adjacent the upper vertebra, a lower load bearing member 3 (figure 7) for being implanted in the intervertebral space within the intact, natural annulus adjacent the lower vertebra, load bearing members are of matching material (column 5 lines 34-37), outer bearing surfaces having a smooth configuration 5/13 (figure 7) , and an inner bearing surfaces 12/25 (figure 7) each having an accurate configuration that cooperate to engage each other and allow for polyaxial rotation and sliding load bearing members relative to each other so that there are multiple outer bearing interfaces 5/13 and an inner bearing interface 12/25 with the outer surfaces of the load bearing members forming the multiple outer bearing interfaces and the inner surfaces 12/25 of the load bearing members forming the inner bearing interface to allow for differential shifting of bearing

interfaces (column 5 lines 22-27).

Regarding claim 43, Marnay disclosed outer bearing surfaces 5/13 comprise smooth, flat surfaces as shown in figure 7.

Regarding claim 44, Marnay disclosed an arcuate inner bearing surfaces comprise a dome surface 25 (figure 7) and a concave recessed surface 12 (figure 7) for receiving the dome surface in engagement therewith with each engaging inner bearing surface being uninterrupted the entire extent thereof for smooth, continuous bearing engagement there between.

Regarding claim 45, Marnay disclosed at least one of the load bearing members has a post (pin like extensions, column 4 lines 57-60) configured to be engaged by a tool for implanting at least the one load bearing member in the intervertebral space.

Regarding claim 46, Marnay disclosed both load bearing members include posts (pin like extensions, column 4 lines 57-60) for a tool, and the arcuate inner bearing surfaces comprise a dome surface 25 (figure 7) and a concave recessed surface 12 (figure 7) sized such that with the dome surface engaged in the concave recessed surface the posts aligned with each other as shown in figure 6, and plate bodies of the load bearing members generally extending in parallel to each other as shown in figure 7, and a predetermined gap spacing is provided between free ends of the aligned posts (column 4 lines 61-65).

Regarding claim 47, Marnay disclosed that the load bearing members each have an elongated configuration with opposite narrow ends (short sides, column 3 lines 64-67, column 4 line 1) and long sides extending between the narrow ends allowing an

incision in the annulus to be kept to a minimum size.

Regarding claim 48, Marnay disclosed that the load bearing members include bodies that are biocompatible metal and plastic.

Erikson teaches the use of PEEK for vertebral implants for load bearing and articular surfaces (column 5 lines 50-64). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention, to include all the implant's structure to be composed of PEEK, as suggested and taught by Erikson, for the purpose of supplying a non compressible substance that minimizes the amount of seizing in articular components (column 5 lines 49-50, 62-65) .

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JOSHUA LEVINE whose telephone number is (571)270-5413. The examiner can normally be reached on Monday-Thursday 7:30am-5:00pm ETA.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Isabella can be reached on 571-272-4749. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/JOSHUA LEVINE/
Examiner, Art Unit 3774

/DAVID ISABELLA/
Supervisory Patent Examiner, Art Unit 3774